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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,300	07/30/2001	Masaaki Matsutani	NAK-056-USA-P	8293
7590 04/21/2004			EXAMINER	
TOWNSEND AND BANTA 601 PENNSYLVANIA AVE., N.W. SUITE 900, SOUTH BUILDING WASHINGTON, DC 20004			LANDREM, KAMRIN R	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,300

Applicant(s)

MATSUTANI ET AL.

Examiner

Kamrin R. Landrem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5 and 7-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/9/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castaneda in view of Clynych (USPN 6,463,351) and Pinchasik (USPN 6,514,285).

Castaneda discloses a nitinol stent (5:14-25) that is customized for a specific patient by means of three-dimensional imaging or computer tomography (10:55-65). Three-dimensional reconstruction is performed by constructing a three dimensional image of the vessel section using the gathered shape information. Castaneda teaches the stent and method of forming a stent as claimed however Castaneda fails to teach the step of creating a mold or model from the three-dimensional information and wrapping the model with wire to produce a stent. Clynych teaches the method of producing a customized prosthetic model by using three-dimensional data to produce a model to produce a prosthetic that provides a custom fit and is less expensive (1:59-63 and 4:40-47). Clynych fails to teach producing a stent by wrapping wire about the model and heating the wire to produce a patient specific prosthetic. Pinchasik teaches the method of forming a stent by wrapping wire about a mandrel and heating the wire to form a radially expandable stent that remembers its specific shape and can return to that shape (1:45-63 and 2:43-48). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the process as disclosed by Castaneda by

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using the data from the three dimensional image to generate a model as taught by Clynych and then using the model in a fashion similar to the mandrel as taught by Pinschasik to wrap the wire about the model and then heat to create a shape memory endoluminal prosthesis that is customized for a specific patient.

Claims 7,8,10,11,14,15,16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clynych in view of Das (USPN 5,554,181) and McCrea (USPN 6,451,047).

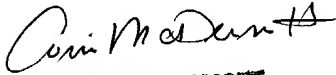
As discussed above, Clynych discloses the method of obtaining the shape information of a patient by forming a three-dimensional mold that matches the patient's specific anatomical geometry. Clynych discloses the method of forming a patient specific prosthesis but fail to teach producing a stent by wrapping wire about the model, compressing it and then heating the wire to produce a patient specific prosthesis. Das teaches a shape memory metal stent that is formed by arranging plurality of wavy circumferential windings 10 and connecting vertical strips 12 onto a mandrel, applying a clamp to tightly claim the ends of the stent around the mandrel (9:15-25). After the mandrel is wrapped and the wires are tightened to the mandrel the stent is heated to a temperature of about 500 °C for about 30 minutes to obtain a desired shape or configuration (9:25+). McCrea further teaches the method of forming a stent including wrapping a tape about the outer surface of the stent to compress the stent structure against the mandrel, heating the stent in a furnace, and then unwinding the wrap to complete the stent formation process. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method disclosed by Clynych to further incorporate the manufacturing steps taught by Das and McCrea to produce a custom fitted medical device in the form of an endoluminal prosthesis.

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With regards to claim 15, it is well known in the endoluminal stent art that Nitinol is comprised of about 55-55% Ni and 44-45% Ti.

Claims 9,12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clynch.

As discussed above, Clynch as modified discloses the claimed invention except for particular values of furnace pressure and heating time. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have adjusted the pressure and time to achieve desirable results, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. (*In re Boesch* 617 F.2d 272, 205 USPQ 215).


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